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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/509,657 | 09/29/2004 | Teruyuki Yatabe | 029650-158 | 2288 |

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POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

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| EXAMINER |
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HUH, BENJAMIN

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| ART UNIT | PAPER NUMBER |
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3767

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/16/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/509,657

Applicant(s)

YATABE ET AL.

Examiner

Benjamin Huh

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/20/07 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Higuichi et al (US Patent No. 7070583 B1). The Higuichi reference discloses in figures 1-10 an injection needle having a first ground facet (3/13) formed on a distal end of a needle tube and at least two ground facets (6/16 & 5/15 respectively) subsequently formed to

provide a needle point, seen as the point between facets 6 & 5 or 16 & 15 which is deemed to be a point of the needle, characterized in that said first ground facet is of a substantially elliptical shape; a plane which crosses said first ground facet perpendicularly thereto and comprises a central axis of said needle tube is regarded as a central plane; and the needle point is not present on said central plane.

With respect to claims 3, 8, & 12, wherein the needle point is located on a boundary between said second ground facet and the third ground facet and wherein an angle α between said first ground facet and a central axis of said needle point, an angle ϕ between said second ground facet and the central axis of said needle point, and an angle θ between said third ground facet and the central axis of said needle point are related to each other by: $\alpha < \phi$, $\alpha < \theta$, and ϕ not equal to θ .

With regards to claims 2, 4, & 10, wherein the minimum distance between said needle point and said central plane is in the range from 3 to 20% of the maximum outside diameter of said first ground facet in the direction of a minor axis thereof as seen in figures 1-10.

With regards to claims 6-7 & 11, wherein the injection needle of Higuchi would be fully capable of piercing a silicone rubber sheet having a thickness of 0.5 mm at a penetration speed of 10 mm/min. with an initial value of the load with respect to a penetration distance being 6 gf/mm or less due to it's size, shape, and ability to work in the environment and since it meets all the structural limitations of the claims.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurtz et al (US Patent No. 4128351). The Kurtz reference discloses in figures 3-7 an injection needle having a first ground facet 84 formed on a distal end of a needle tube and at least two ground facets (60 & 72) subsequently formed to provide a needle point 66, characterized in that said first ground facet is of a substantially elliptical shape; a plane which crosses said first ground facet perpendicularly thereto and comprises a central axis of said needle tube is regarded as a central plane; and the needle point is not present on said central plane, see more specifically figures 3-4.

With respect to claims 3, 8, & 12, wherein the needle point is located on a boundary between said second ground facet and the third ground facet and wherein an angle α between said first ground facet and a central axis of said needle point, an angle ϕ between said second ground facet and the central axis of said needle point, and an angle θ between said third ground facet and the central axis of said needle point are related to each other by: $\alpha < \phi$, $\alpha < \theta$, and ϕ not equal to θ .

With regards to claims 2, 4, & 10, wherein the minimum distance between said needle point and said central plane is in the range from 3 to 20% of the maximum outside diameter of said first ground facet in the direction of a minor axis thereof as seen in figures 1-10.

With regards to claims 6-7 & 11, wherein the injection needle of Kurtz would be fully capable of piercing a silicone rubber sheet having a thickness of 0.5 mm at a penetration speed of 10 mm/min. with an initial value of the load with respect to a

penetration distance being 6 gf/mm or less due to it's size, shape, and ability to work in the environment and since it meets all the structural limitations of the claims.

Claims 1-2, 6, & 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon, III (US Patent No. 5064411). The Gordon reference discloses in figures 2-3 an injection needle having a first ground facet 15 and at least two facets subsequently, formed by the serration, to provide a needle point 18, wherein the claim does not state that the needlepoint is created between the two facets, characterized in that said first ground facet is of a substantially elliptical shape; a plane that crosses said first ground facet perpendicularly thereto and comprises a central axis of said needle tube is regarded as a central plane; and the needle point is not present on said central plane. The examiner would also like to note that the terms "ground facet" is product by process and the facets are not required to be ground but are fully capable of being ground.

With regards to claim 2, wherein the minimum distance between said needle point and said central plane is in the range from 3 to 20% of the maximum outside diameter of said first ground facet in the direction of a minor axis thereof as seen in figures 1-10.

With regards to claim 6, wherein the injection needle of Gordon would be fully capable of piercing a silicone rubber sheet having a thickness of 0.5 mm at a penetration speed of 10 mm/min. with an initial value of the load with respect to a penetration distance being 6 gf/mm or less due to it's size, shape, and ability to work in the environment and since it meets all the structural limitations of the claims.

With regards to claim 8, wherein an angle α between said first ground facet and a central axis of said needle point, an angle ϕ between said second ground facet and the central axis of said needle point, and an angle θ between said third ground facet and the central axis of said needle point are related to each other by: $\alpha < \phi$, $\alpha < \theta$, and ϕ not equal to θ .

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

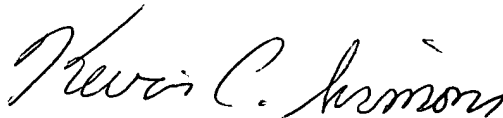
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

A handwritten signature in cursive script, reading "Kevin C. Sirmons".